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FREQUENTLY ASKED QUESTIONS

What is the status of sodium fluoride at the Cancer Imaging Program?

What is the regulatory status of sodium fluoride?

How can I use sodium fluoride in my clinical trial?

Can I make my own sodium fluoride?

Can I buy sodium fluoride from someone?

How can NCI help?

For additional information

What is the status of sodium fluoride at the Cancer Imaging Program?

We have an established IND (9/2008) for sodium fluoride that we actively encourage investigators to cross-file on

- We freely provide an investigators drug brochure for anyone to use <http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources>,
- We have letters of authorization from some commercial suppliers to provide sodium fluoride under a Drug Master File (DMF)
- We encourage academic and pharmaceutical investigators to evaluate sodium fluoride for diagnosis and response to treatment of bone metastases
- We anticipate that the data resulting from wider availability of this agent will support a New Drug Application (NDA).

What is the Regulatory Status of Sodium Fluoride?

Sodium fluoride is currently an investigational PET agent for bone scans. In the early 70's, it was approved for marketing, but the NDA was withdrawn by the holder. It was not withdrawn for reasons of safety or efficacy and in 2000, the FDA ruled that either ANDA or NDA could be submitted for this drug (March 10, 2000. *Federal Register*.65:12999-13009). An Investigational New Drug (IND) Exemption from the FDA will permit you to make and use sodium fluoride. IND information can be found here:

http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm

How can I use sodium fluoride in my clinical trial?

In order to use sodium fluoride, you must hold an IND or have your basic science trial approved by your Institution's RDRC (Radioactive Drug Research Committee). In either case, you must have your trial approved by an Institutional Review Board (IRB).

Can I make my own sodium fluoride?

If you have appropriate facilities (cyclotron, radiochemistry lab and personnel, capacity to manufacture PET agents for human use), you can make sodium fluoride. Your chemistry procedures must be acceptable to FDA for your IND or to the RDRC, and to the IRB. Since sodium fluoride has a USP monograph, you may be able to comply with it and meet FDA requirements.

Can I buy sodium fluoride from someone to use in my trial?

Some commercial firms do provide sodium fluoride for research use. That material can be used in your clinical trial if the supplier has a Drug Master File (DMF) on file with the FDA for this agent, which would permit use of this material in your IND-approved trial with a letter of authorization or if you have a letter of authorization to our IND, which contains appropriate authorizations.

How can NCI help?

NCI can assist in two ways. NCI holds an IND for sodium fluoride that is based on DMF letters from commercial manufacturers and the FDA's determination in 2000 that there was adequate information on safety and efficacy to permit NDA filings. CIP will provide a Letter of Authorization (cross-file letter) to the FDA in conjunction with your IND that can simplify your IND application. This letter will substitute for the Pharmacology, Toxicology, Radiation Dosimetry and Previous Human Experience sections of the IND. Investigators drug brochure for sodium fluoride for use in clinical trials are available on the Cancer Imaging Program (CIP) website.

<http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources>

If you do purchase sodium fluoride from a company that holds a DMF, their Letter of Authorization will substitute for the Chemistry, Manufacturing, and Control section of your IND.

For additional information

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